

Best Available Copy

NOV-21-1996 13:41 FROM SCULLY SCOTT

TO

917033057401

P.02

PATENTS

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Helena P. Selavry Examiner: D. Ware
Serial No.: 08/421,641 Art Unit: 1808
Filed: April 13, 1995 Docket: 92493
For: METHOD OF TREATING DISEASE
USING SERTOLI CELLS AND
ALLOGRAFTS OR XENOGRAFTS

Assistant Commissioner for Patents
Washington, DC 20231

DECLARATION PURSUANT TO 37 C.F.R. §2.131

Sir:

I, Helena P. Selavry, hereby declare that:

1. I am the applicant of United States Patent Application Serial No. 08/421,641, filed April 13, 1995, which application is a continuation-in-part of United States Patent Application Serial No. 08/211,695 filed April 13, 1994.

2. The publication entitled, (1993) "Sertoli Cell-Enriched Fractions in Successful Islet Cell Transplantation", Cell Transplantation 2:123-129 (hereinafter "Selavry, et al."), has been identified by the Examiner (through applicant's Information Disclosure Statement). The Selavry, et al. reference was published (mailed) and thus available to the public no earlier than April 13, 1993.

3. The invention disclosed and claimed in the above-identified application was completed in the United States by me and under my direct supervision and control prior to the publication of the Selavry, et al. reference.

4. As evidence of the completion of the above invention, annexed hereto is Exhibit A. Exhibit A consists of a photocopy of laboratory notebook pages, of work performed in my laboratory at the Department of Veterans Affairs Medical Center in Memphis, Tennessee and in the Department of Medicine

Best Available Copy

NOV-21-1996 13:42 FROM SCULLY SCOTT

TO

917033057401 P.03

at the University of Tennessee in Memphis, Tennessee, showing reduction to practice of the claimed invention. The activity contributing to this reduction to practice was conducted by myself or by other scientists and/or technicians working under my direct supervision and control prior to the publication of Selavry, et al. Data not pertinent to this invention and dates have been redacted in preparation of this exhibit.

5. The reduction to practice evidenced by Exhibit A consisted of successfully creating an immunologically privileged site in the renal subcapsular space of a rat by injection of Sertoli cells, and transplantation of insulin-producing islet cells in the renal subcapsular space.

6. Specifically, islets were isolated from a Sprague-Dawley (S-D) donor rat and then incubated in CMRL-1064 media at 37°C for four days. A highly purified Sertoli cell preparation, free of Leydig and germ cells, was isolated from a PVG male rat less than 30 days old. The Sertoli cells were transplanted under the left renal capsule without incubation. The recipient was a PVG rat made diabetic by a single injection of 55 mg/kg streptozotocin. The rat was transplanted with Sertoli cells obtained from two testis. This data clearly showed that blood sugar (BS), urine glucose (UG) and total urine glucose (UT) were elevated after streptozotocin administration, indicating hyperglycemia. (See Days 0-1 identified in the left column of the notebook pages.) By Day 3 post-transplant blood sugar and urine glucose dropped significantly and stayed depressed following administration of the transplanted islet and Sertoli cells in accordance with the present invention, indicating normoglycemia. (See Days 4-323;.

7. I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further

Best Available Copy

NOV-21-1996 13:42 FROM SCULLY SCOTT

TO

917033057401 P.04

that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date: November 21, 1996 Helena P. Selawsky
Helena P. Selawsky

SUBSTITUTE DECLARATION FOR UTILITY PATENT APPLICATION

AS A BELOW-NAMED INVENTOR, I HEREBY DECLARE THAT:

My residence, post office address, and citizenship are as stated below next to my name.

I believe I am the original, first and joint inventor of the subject matter which is claimed and for which a patent is sought on the invention entitled: METHODS OF TREATING DISEASE USING SERTOLI CELLS AND ALLOGRAFTS OR XENOGRAFTS, the specification of which is attached hereto unless the following box is checked:

☒ was filed on 08 November 1996 as United States Application Serial No. 08/747,122.

I HEREBY STATE THAT I HAVE REVIEWED AND UNDERSTAND THE CONTENTS OF THE ABOVE-IDENTIFIED SPECIFICATION, INCLUDING THE CLAIMS, AS AMENDED BY ANY AMENDMENT REFERRED TO ABOVE.

I acknowledge the duty to disclose information which is material to the patentability as defined in 37 C.F.R. § 1.56.

I hereby claim foreign priority benefits under 35 U.S.C. § 119(a)-(d) or § 365(b) of any foreign application(s) for patent or inventor's certificate, or § 365(a) of any PCT International application which designated at least one country other than the United States listed below and have also identified below, by checking the box, any foreign application for patent or inventor's certificate, or PCT International application having a filing date before that of the application on which priority is claimed:

Application Serial No.	Country	Filing Date (day/month/year)	Priority Claimed?
PCT/US94/04044	PCT	13 April 1994	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No

I hereby claim benefit under 35 U.S.C. § 119(e) of any United States provisional application(s) listed below:

Application Serial No.	Filing Date
-	-

I hereby claim the benefit under 35 U.S.C. § 120 of any United States application(s), or § 365(c) of any PCT International application designating the United States, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT International application in the manner provided by the first paragraph of 35 U.S.C. § 112, I acknowledge the duty to disclose information which is material to patentability as defined in 37 C.F.R. § 1.56 which became available between the filing date of the prior application and the national or PCT International filing date of this application.

Application Serial No.	Filing Date	Status
08/421,641 (US Patent 5,725,854)	13 April 1995 (Issued 10 March 1998)	<input checked="" type="checkbox"/> Patented <input type="checkbox"/> Pending <input type="checkbox"/> Abandoned
08/211,695	13 April 1994	<input type="checkbox"/> Patented <input type="checkbox"/> Pending <input checked="" type="checkbox"/> Abandoned

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under § 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date

Name: Helena P. Selawry
Residence: Memphis, Tennessee
Citizenship: United States of America
Post Office Address: 7041 Woodlake Drive, Memphis, Tennessee 38119

Date

Name: Don Frank Cameron
Residence: Lutz, Florida
Citizenship: United States of America
Post Office Address: 18206 Clear Lake Drive, Lutz, Florida 33549

In response to applicant's argument on page 17, lines 6- 11, note that claims 15 and 31 recite " ... wherein said tool or appliance is releasably secured to said attachment post by means of a coupling". Note in figure 14, the foot member 14 is a tool which is releasably secured to post 11 by means of a coupling (the socket 45 forms the recited coupling means). In response to applicant's argument on page 19, lines 7- 13, note on figure 5 that a portion of cuff 51 forms the recited helix (note attached figure 5). In response to applicant's argument on page 20, the last paragraph, " because of the helical nature of the brace, the wrist is free to flex.....", note in figure 5 of Stephen that the wrist is free to flex from side to side and up and down when a child or a person with a small forearm uses the device. Also, from applicant's figure 1a, a user's wrist is free to flex or not depends on the curvature of the helix relative to the size of a forearm of a user.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

Art Unit: 3764

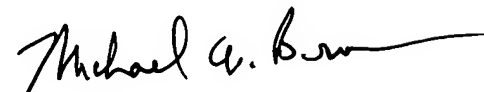
the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Huong Q. Pham whose telephone number is (571) 272-4980. The examiner can normally be reached on 6:30 AM - 3:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gregory Huson can be reached on (571) 272 - 4887. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

July 7, 2008



MICHAEL A. BROWN
PRIMARY EXAMINER

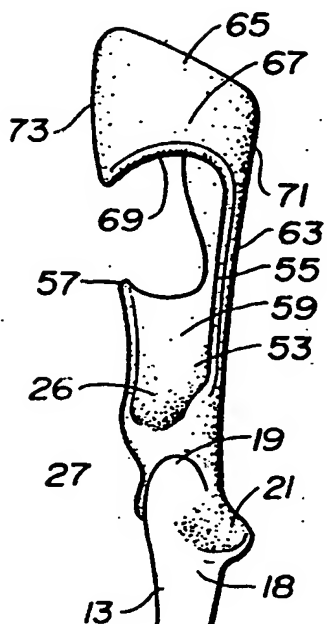


FIG. 2

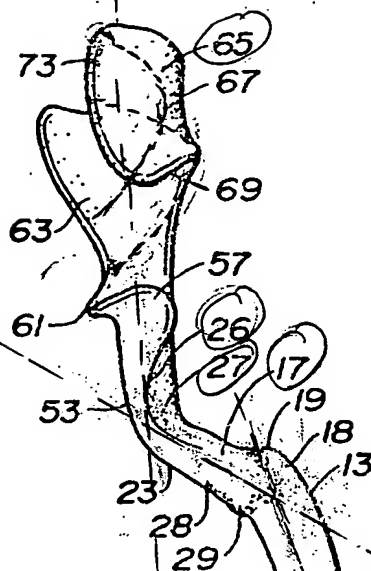


FIG. 5